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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,431	04/19/2000	Katherine W. Osteryoung	920905.90041	3961

26735 7590 04/16/2002

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,431

Applicant(s)

OSTERYOUNG, KATHERINE W.

Examiner

Anne Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-8 and 10-28, to the extent they read on a nucleic acid of SEQ ID NO:1) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the proteins encoded by SEQ ID NOs:1 and 3 have 92% sequence identity and are analogous genes from different plants; they thus represent the same invention. Applicant also argues that a search on the subject matter of one should encompass the subject matter of the other. This is not found persuasive because SEQ ID NOs:1 and 3 differ in composition, structure and function. Applicant is required to delete non-elected sequences. Claims 1-8 and 10-28 are examined to the extent they read on SEQ ID NO:1. Claim 9 is withdrawn from consideration as being drawn to a non-elected invention. The requirement is still deemed proper and is therefore made FINAL.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The draftsman has approved the drawings as submitted.
4. The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

Response to Amendment

5. The objection to claims 1 and 14 because they recite "cause" in lines 6 and 12, instead of "causes" is WITHDRAWN in light of amendments to the claims.

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6. The rejection of claim 8 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is WITHDRAWN in light of amendments to the claim to specify that the DNA sequence is isolated.

Response to Arguments

7. The rejection of claims 8 and 27-28 under 35 U.S.C. 102(b) as being clearly anticipated by Sato et al (1998, DNA Res. 5:41-54), IS WITHDRAWN as the sequence available in GenBank at the time the paper was published is not longer available, and the only available sequence was submitted after the filing date of the instant application.

Claim Rejections - 35 USC § 112

8. Claims 1, 4, 7, 10-12, 14, 17, 20, 23-24 and 27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *Arabidopsis* MinD gene encoding SEQ ID NO:2, plants transformed with that gene, and methods of using that gene to alter size, shape and/or number of plastids, does not reasonably provide enablement for any MinD coding sequence from any source, plants transformed with any MinD coding sequence, or methods of using any MinD coding sequence to alter size, shape and/or number of plastids, as stated in the prior Office action. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments filed 17 January, 2002, have been fully considered but they are not persuasive. Applicant urges that they have made the novel discovery of plant MinD genes.

Applicant argues that the specification described methods that allow identification of a MinD gene

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from any plant and that similarity analysis can be used to identity MinD genes from plants other than *Arabidopsis* or *Tagetes*. Applicant argues that the claims cover a representative sample of those genes. Applicant also urges that insertion of sense or antisense in any plant is enabled by the specification.

This is not found persuasive because the instant specification fails to provide guidance for plant MinD sequences encoding MinD proteins with 50% identity to SEQ ID NO:2. The specification also fails to describe the hybridization and wash conditions and probes, and the PCR conditions and primers required to isolate this multitude of sequences.

SEQ ID NO:1 encodes a 326 amino acid long protein. Making all possible **single** amino acid substitutions in an 326 amino acid long protein like that encoded by SEQ ID NO:1 would require making and analyzing 19^{325} nucleic acids. Because nucleic acids encoding proteins with 50% identity to SEQ ID NO:1 would have many more than a single substitution, nucleic acids with many more substitutions would need to be made and analyzed. Applicant has only described two sequences, and has not provided guidance for which amino acids of SEQ ID NO:2 can be altered to which other amino acids, and which amino acids must not be changed.

9. Claims 1-7 and 10-26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alteration of size, shape and/or number of plastids in *Arabidopsis* via antisense expression of SEQ ID NO:1, does not reasonably provide enablement for alteration of size, shape and/or number of plastids in any plant via antisense expression of SEQ ID NO:1, as stated in the prior Office action. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Applicant's arguments filed 17 January, 2002, have been fully considered but they are not persuasive. Applicant urges that the specification teaches that the phenomena of manipulation of plastid number can be made in other plants.

This is not found persuasive because all MinD genes that encode proteins with 50% identity to SEQ ID NO:2 were not taught by the instant specification, and Colliver et al (1997, Plant Mol. Biol. 35:509-522) teaches that antisense constructs that are not completely homologous to the target gene can have very unpredictable effects. The specification only teaches a method of altering the size, shape or number of plastids *Arabidopsis* via antisense inhibition of the *Arabidopsis* MinD gene with an antisense construct comprising the *Arabidopsis* MinD gene. Antisense inhibition of other plants was not taught. Thus, the unpredictability of antisense inhibition of genes that are not completely homologous is not overcome. Altering the size, shape or number of plastids in any plant by transformation with any antisense MinD gene that encodes a protein with 50% identity to SEQ ID NO:2 is not enabled. Altering the size, shape or number of plastids in any plant by transformation with any sense MinD gene that encodes a protein with 50% identity to SEQ ID NO:2 is also not enabled, because the genes are not taught.

10. Claims 1, 4, 7, 10-12, 14, 17, 20, 23-24 and 27 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the prior Office action.

Applicant's arguments filed 17 January, 2002, have been fully considered but they are not persuasive. Applicant urges that the claims have been amended to claim a MinD gene encoding a MinD protein with 50% sequence identity to SEQ ID NO:2.

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This is not found persuasive because the instant specification fails to describe the sequence of the multitude of MinD genes encoding a MinD protein with 50% sequence identity to SEQ ID NO:2. No description is provided as to the structural features that distinguish all such plant MinD genes from other plant genes, and no description is provided as to essential motifs that define MinD genes.

See *In re Shokal*, 113 USPQ 283, (CCPA 1957) at pg 285

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ...

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

11. Claims 1,4, 7, 10-12, 14, 17, 20, 23-24 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "the MinD gene encoding a protein having at least a 50% sequence identity with SEQ ID NO:2". Thus, such phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

12. Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the

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invention. Dependent claims are included in the rejection. In claim 24, the phrase "the plant having" should be replaced with --thereby producing a plant with--.

13. Claims 1-26 are free of the prior art, given the failure of the prior art to teach or fairly suggest methods of altering the size, shape and/or number of plastids in plant cells by transformation with a sense or antisense MinD gene, the constructs used in that method, or the plants or seeds so obtained. The prior art also fails to teach or suggest a nucleic acid of SEQ ID NO:1.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
April 11, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

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